K944036 OCT -2

510(k) SUMMARY FOR THE STERImaster AUTOCLAVE

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Classification Name:	Sterilizer, Steam
Common/Usual Name:	Sterilizer, Steam
Trade/Proprietary Name:	STERImaster Autoclave
Establishment Registration Number:	8043629
Classification:	Class II under 21CFR880.6880

Predicate Device for Substantial Equivalence:
This product is similar in design, composition and function to the STAT*IM* Cassette Autoclave® manufactured by SciCan, Division of Lux and Zwingenberger Ltd., which was the subject of Premarket Notification No. K910241B. The STAT*IM* is presently being marketed. The main difference between the two, besides the smaller chamber in STERImaster, is the sterilization chamber itself. The STAT*IM* uses a two-piece cassette which is manually inserted into the unit. The STERImaster features a one-piece chamber which is automatically retracted into the unit. A seal inside the unit descends onto the chamber, forming a closed sterilization vessel. The smaller size has necessitated slightly different cycle parameters, which are described below.

Technical Description:
The STERImaster Autoclave is a fast, efficient table-top unit for the sterilization of health care instruments. The STERImaster uses the internationally accepted standard of steam sterilization at a specific temperature for a specific time. Low power requirements (110 Volts, 60 Hz, 1300 Watts) mean that the unit can be plugged into any grounded 15 Amp circuit.

The unit measures 384 mm long, 292 mm wide and 282 mm high, while the sterilization chamber measures 190 mm long, 90 mm wide and 53 mm high.

An optional printer is offered which provides a permanent record of the cycle parameters. Printed data includes date and time, cycle counter, cycle chosen, the start time of each cycle phase (described below), the temperature and pressure at 30 second intervals during the sterilization phase, and any error conditions encountered.

The STERImaster features a removable stainless-steel drawer, which holds the open-topped thin-walled stainless-steel sterilization chamber. At the start of the sterilization cycle, the drawer automatically retracts into the insulated, lightweight laminated steel containment system. Steam enters through a small hole in the seal and exhausts through a hole at the bottom of the chamber. A microprocessor-activated valve controls the steam exhaust. The chamber is designed to distribute steam from the top to the bottom, creating a wall of steam which moves downward, driving out trapped air. The chamber is positioned in the STERImaster at an angle, allowing condensed steam to collect in the rear corner and drain from the machine through the exhaust valve.

During operation, measured quantities of distilled water are drawn by the pump and injected, on demand, into the steam generator. The steam created here travels directly to the chamber. The steam temperature is monitored by two calibrated thermocouples; one in the chamber and one in the steam generator. The chamber thermocouple is located at the exhaust port, which is

equivalent to the drain in traditional autoclaves, and is therefore the coldest spot in the chamber. Power to the steam generator is modulated by a microprocessor-based control system, based upon the temperature in the sterilization chamber. This, and internal baffles in the steam generator, combine to ensure a supply of high-quality steam, at the correct temperature, to the sterilization chamber.

The STERImaster offers three microprocessor-controlled sterilization cycles. The first cycle sterilizes at 132°C for 3.5 minutes and is used for solid metal instruments. The second cycle sterilizes at 132°C for 5 minutes and is used for dental handpieces and hollow metal instruments of all types. The third cycle sterilizes at 121°C for 30 minutes and is used for rubber, plastic or heat sensitive instruments.

The STERImaster sterilization cycles are broken down into five phases: 1) warm-up, 2) conditioning, 3) pressurizing, 4) sterilizing, 5) venting. During the first phase, steam feeds into the chamber where it begins to purge the air through the open exhaust valve. Successive pulses of steam rapidly raise the temperature inside the chamber and drive the air out. Depending on the cycle selected, the second phase consists of a series of deep purges, during which the exhaust valve opens until the temperature falls from the sterilization temperature to 115 °C or 110 °C. The exhaust valve closes and the unit repressurizes to the sterilization temperature. These purges are designed to expel the remaining air from the chamber. When these purges finish, the third phase begins. Pressure and temperature inside the chamber rise, and the exhaust valve opens periodically to expel condensate. The fourth phase begins when the desired sterilization temperature is reached, and continues for the required time period during which the sterilization temperature is maintained precisely. At the end of this period, the exhaust valve opens and the pressure inside the chamber falls to atmospheric pressure. This is the fifth phase. At this point, the drawer automatically opens. The instruments can then be removed when dry and cool.

The use of a forced steam supply enables better air removal, better quality control of sterilization conditions, and less oxidation of metal instruments in the chamber. The low mass of the sterilization chamber allows it to heat quickly. Therefore, the net time spent on heat-up and cool-down is minimized, though the duration of sterilization conditions, of course is the same for all autoclaves. This benefit speeds the cycle and therefore lessens damage to instruments.

The safety and effectiveness problems which attend the STERImaster Autoclave are typical of all steam autoclaves. For example, caution must be exercised not to over-pack the autoclave, thereby inhibiting the free flow and even penetration of steam. By and large however, every error condition is detectable by the unit and will result in an incomplete cycle and a warning on the display. The pressure vessel safety aspects are less serious in the STERImaster than in other typical table-top sterilizers because of its small volume and laminated steel support structure. There is no door and hinge mechanism which can fail or be partially closed, presenting the type of explosion hazards reported for pressure-cooker type autoclaves with front-hinge doors.

Relevant Standards:
Currently, there are no standards in North America related to small, table-top autoclaves of unique construction, such as the STERImaster. It is therefore necessary to examine the most important standards for larger autoclaves, and extract the safety and performance standards which apply. The STERImaster Autoclave was designed according to the AAMI Standards and Recommended Practices for Sterilization, and ST8-1988. It also conforms to UL1262 and CSA C22.2-151M, both laboratory equipment safety standards.

Microbiological Evaluations:
Extensive tests by Sterization Technical Services using *Bacillus Stearothermophilus* spores as the microbiological challenge, have determined the sterilization effectiveness of each of the cycles according to the Test Protocol included in the main body of the submission. The calculated F_0 values are included in the following table:

Cycle	Nominal Temperature (°C)	Time (min.)	F_0 (min.)
Solid instruments	132	3.5	85.91
Handpieces	132	5	122.74
Rubber and Plastics	121	30	29.32

By using the well-established steam sterilization process, and demonstrating a large margin of safety in the destruction of *Bacillus Stearothermophilus* spores, it can be concluded that the STERImaster Autoclave is substantially equivalent to the STATIM Cassette Autoclave®, as well as other table-top sterilizers currently on the market.